K121293

Omega Medical Imaging, LLC

JUL 2 6 2012

510(k) SUMMARY

Company Name:	Omega Medical Imaging, LLC
Address:	675 Hickman Circle Sanford, FL 32771
Telephone No:	407-323-9400
Registration No.:	1052701
Contact person:	Brian J. Fleming
Date Prepared:	20 April 2012
Device (trade) name:	CS-*series*-FP *with 3030+ Option* radiographic/fluoroscopy system
Common/usual name:	Image Intensified Fluoroscopic X-ray System
Classification Name:	Solid State X-ray Imager, Class II, 90 MQB Angiographic X-ray System, Class II, 90 IZI
Classification Panel:	Radiology
CFR Section:	892.1650 and 892.1600
Device Class:	Class II
Device Code:	90 MQB, 90 IZI

Predicate device(s):

- Omega Medical Imaging CS-*series*-FP (K100102)

Device description:

The Omega Medical Imaging, LLC. CS-*series*-FP systems currently incorporate a 19.8cm x 19.8cm solid-state flat-panel detector (FPD) as an option. This 510(k) submission adds a larger format (29.8cm x 29.8cm) flat-panel detector as an additional option. The CS-*series*-FP fluoroscopy single and dual plane x-ray imaging systems are configured with a floor mounted C-arm and a patient table. The dual plane systems incorporate a ceiling suspended C-arm into the system. The flat-panel image detector utilizes a cesium iodide scintillator coupled to an amorphous silicon TFT panel. The captured digital image is processed by the acquisition system which includes image processing, viewing functions, local storage, and DICOM compatibility.

Materials: The solid-state x-ray imager (FPD) construction and materials comply with UL2601-1, IEC60601-1, CSA 22.2 No. 601.1-M90, and is CE Marked. The imager is classified by Underwriters Laboratories.

Intended use:

- The Omega Medical Imaging, LLC. CS-*series*-FP *with 3030+ Option* systems are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

Comparison with Predicate Devices:

- The Omega Medical Imaging large format option to the CS-*series*-FP system utilizes identical technology of the above mentioned predicate device. The input scintillator is Cesium Iodide coupled to a Thin-Film-Transistor (TFT) panel. The image processing is achieved with conventional computer based image processing systems. It is the opinion of Omega Medical Imaging that the CS-*series*-FP *with 3030+ Option* utilizing the larger format FPD detector is essentially equivalent to the existing Omega Medical Imaging cleared CS-*series*-FP system utilizing the smaller format FPD.

Substantial Equivalence:

- SE was determined on non-clinical performance testing. Included in this report is detailed data comparing performance with the existing Omega Medical Imaging CS-*series*-FP system utilizing the 19.8cm x 19.8cm format FPD image acquisition system. The tests that were performed utilized commercially available Test Objects that include low-contrast objects with varying absorbers simulating different patient sizes, spatial and temporal resolution test objects, and dynamic range test objects. Also included is the "Non-clinical Considerations" of the flat-panel detector.

  It is the opinion of Omega Medical Imaging that the CS-*series*-FP *with 3030+ Option* with the larger format FPD (29.8cm x 29.8cm) is essentially equivalent to the cleared Omega Medical Imaging CS-series-FP (K100102) smaller format detector systems.

Safety information:

- The Omega CS-*series*-FP *with 3030+ Option* systems comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega *CS-series*-FP *with 3030+ Option* systems comply with the international safety standards IEC 60601-1, IEC 60101-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32, and IEC 60601-2-43.
- The Omega *CS-series*-FP *with 3030+ Option* systems comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90

Conclusion:

The Omega CS-*series*-FP *with 3030+ Option* systems with the larger format (29.9cm x 29.9cm) FPD do not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Omega considers the CS-*series-FP with 3030+ Option* systems with this larger format flat-panel detector to be substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Mr. Brian J. Fleming
President & CEO
Omega Medical Imaging, LLC
675 Hickman Circle
SANFORD FL 32771

Re: K121293
Trade/Device Name: CS-*series*-FP with 3030+ Option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and OWB
Dated: April 20, 2012
Received: May 1, 2012

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

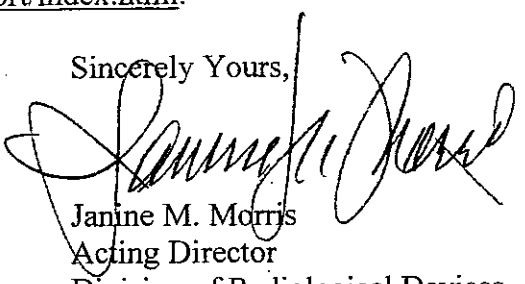
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: CS-*series*-FP *with 3030+ Option*

Indications for Use:

The Omega Medical Imaging, LLC CS-*series*-FP *with 3030+ Option* systems are intended for use in radiographic/fluoroscopic application including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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